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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Golam Haroon, President
Eastland Seafood, Inc.
5602 56th Street
Maspeth, NY 11378

February 2, 2005

Ref: NYK-2005-05

Dear Mr. Haroon:

On January 5 and 6, 2005, the Food and Drug Administration (FDA) conducted an inspection of your seafood importing and distribution facility located at the above address. The inspection was conducted to determine your firm's compliance with the FDA's seafood Hazard Analysis and Critical Control Points (HACCP) regulations, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," Title 21, *Code of Federal Regulations*, Part 123 (21 CFR Part 123).

During our inspection, the investigators observed serious deviations from the special requirements for imported fish and fishery products (21 CFR 123.12). In accordance with 21 CFR 123.6(g), failure of a processor to operate in accordance with the requirements of 21 CFR Part 123, renders the fish or fishery products of that processor adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The FDA investigators provided you with a copy of the FDA 483, Inspectional Observations, which presents their evaluation of your firm's performance regarding various aspects of the HACCP requirements. The deviations of concern to us include the following:

1. You must either obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the FDA that covers the fish or fishery products you import, 21 CFR 123.12(a)((1), or have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, FDA does not have an applicable active MOU with [redacted] and your firm has product specifications for frozen Hilsa fish and frozen Rohu fish imported from [redacted] that do not adequately address the food safety hazards of histamine formation (Hilsa) and

chemical contaminants (Hilsa and Rohu) that are reasonably likely to be presented by these products.

2. You must either obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the FDA that covers the fish or fishery products you import, 21 CFR 123.12(a)((1), or implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, FDA does not have an applicable active MOU with [redacted], and your firm performed an affirmative step for frozen Hilsa fish and frozen Rohu fish manufactured by [redacted] that was not adequate. Specifically, you chose to maintain on file a written guarantee from the foreign processor that the imported fish is processed in accordance with the requirements of the seafood HACCP regulation as your affirmative step. In order to use this affirmative step (21 CFR 123.12 (a)(2)(ii)(D)), you must also maintain on file a copy, in English, of the foreign processor's HACCP plan in addition to the written guarantee. During the inspection, your firm was unable to provide a copy of the foreign processor's HACCP plan for review.

Please note that the above identified deviations were previously brought to your attention in our letter of August 25, 2003.

These deviations and the Inspectional Observations (Form FDA 483) that was presented to, and discussed with, Ms. Khlada Rahman, Manager, at the conclusion of the inspection are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all fish and fishery products imported, processed, and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported fish and fishery products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

You should send your reply to Attn: Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, you can contact Mr. Goldwitz by telephone at (718) 340-7000 ext. 5582.

Sincerely,

Robert L Hart

Jerome G. Woyshner
District Director

Enclosure: Form FDA 483 dated January 6, 2005